Contains Nonbinding Recommendations

Draft Guidance on Gabapentin

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Gabapentin

Dosage Form; Route: Tablet (once daily); oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 600 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: None

2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 600 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: Refer to the amantadine hydrochloride tablet draft guidance for additional information regarding fed studies

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Analytes to measure (in appropriate biological fluid): Gabapentin in plasma

Bioequivalence based on (90% CI): Gabapentin

Waiver request of in vivo testing: 300 mg based on (i) acceptable bioequivalence (BE) studies on the 600 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Please note that for test products which are not proportionally formulated, a fed BE studies on both 300 mg and 600 mg strengths, since the two strengths are not proportional, and food effects may be different for each strength.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).